

REMARKS

This responds to the Office Action dated January 27, 2006, and the references cited therewith.

Claims 11, 16, 21, 30, 40, and 44 are amended. Claims 1-45 remain pending in this application.

Information Disclosure Statement

Applicant filed a Information Disclosure Statement ("IDS") on March 23, 2005. The Examiner partially initialed the Form 1449 that accompanied this IDS. Specifically, Re. 37,463 and EP 0791372A1, were not indicated as considered by the Examiner. Applicant encloses herewith a copy of the initialed Form 1449 for the Examiner's reference and a copy of the stamped returned postcard indicating that the documents were received by the USPTO. Applicant requests that the Examiner consider the documents and return a completely initialed copy of the Form 1449 with the next USPTO communication.

U.S. Patent No. 4,711,251B1 was inadvertently listed twice on the 1449 Form filed March 23, 2005. The second occurrence of 4,711,251, which was crossed out by the Examiner, need not be considered.

Objection to the Drawings

The drawings were objected to as failing to comply with 37 C.F.R. 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "helix 100". Applicant has amended the specification to refer to "helix 30," instead of helix 100.

§112 Rejection of the Claims

Claims 11, 40, and 44 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claims 11, 40, and 44 to overcome the rejection.

§102 Rejection of the Claims

Claims 1, 3-4, 6, 12-14, 16, 18-20, 30 and 33-34 were rejected under 35 U.S.C. § 102(b) as being anticipated by Stokes (U.S. Patent No. 4,506,680).

Claims 1, 3-4, 6, and 12-14

Applicant traverses the anticipation rejection of claims 1, 3-4, 6 and 12-14. “Anticipation requires the presence in a single prior reference disclosure of each and every element of the claimed invention, arranged as in the claim.” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)). In this case, Applicant cannot find in the cited reference: “wherein the electrode includes a coating on at least a portion of a surface of the electrode, the coating including two or more layers, with a first layer adjacent the surface of the electrode including an insulative material and a second layer adjacent the first layer including at least one pharmacological agent,” as recited in claim 1. In contrast, Stokes discusses a sintered metal porous coating 34 and a plug 38 that includes drugs that can elute through coating 34. However, sintered metal porous coating 34 is not insulative, as claimed.

Claims 3-4, 6, and 12-14 include each limitation of their parent claim and are therefore also not anticipated by the cited reference. Reconsideration and allowance is respectfully requested.

Claims 16 and 18-20

Applicant has amended claim 16 to better describe the subject matter recited in the claim. Applicant believes claim 16 is not anticipated by the cited reference, since the cited reference

does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited reference: “wherein an outer surface of the electrode is coated with two or more layers comprising a first layer including an insulative material and a second layer over the first layer, the second layer including at least one pharmacological agent,” as recited in claim 16. As discussed above, Stokes discusses a sintered metal porous coating 34 and a plug 38 that includes drugs that can elute through coating 34.

Claims 18-20 include each limitation of their parent claim and are therefore also not anticipated by the cited reference. Reconsideration and allowance is respectfully requested.

Claims 30 and 33-34

Applicant has amended claim 30 to better describe the subject matter recited in the claim. Applicant believes claim 30 is not anticipated by the cited reference, since the cited reference does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited reference: “an inner layer including a pharmacological agent in a polymer matrix for regulated, chronic release of the pharmacological agent and an outer layer including only a pharmaceutical agent such that the pharmaceutical agent of the outer layer is exposed to tissue upon implant of the electrode, and a middle layer between the inner layer and the outer layer, the middle layer including a porous polymer barrier,” as recited in claim 30.

Claims 33-34 include each limitation of their parent claim and are therefore also not anticipated by the cited reference. Reconsideration and allowance is respectfully requested.

Claims 35-36 and 41-42 were rejected under 35 U.S.C. § 102(b) as being anticipated by Vachon et al. (U.S. Patent No. 5,324,324).

Applicant traverses the anticipation rejection of claims 35-36 and 41-42 since the cited reference does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited reference: coating an electrode with a first layer, wherein the first layer comprises a polymeric base coat; and coating the electrode with a second layer, wherein the second layer comprises a polymer and at least one pharmacological agent, and at least partially coats the first layer, as recited in claim 35. The Office Action asserts that, in Vachon, “a first

layer comprises a polymeric base coat (column 3, lines 31-33).” (Page 5 of Office Action). However, this cited section of Vachon discusses the sheath 24 of the lead of Vachon. Nowhere in Vachon is the sheath 24 at least partially covered with a second layer comprising a polymer and at least one pharmacological agent, as recited in claim 35.

Claims 36 and 41-42 include each limitation of their parent claim and are therefore also not anticipated by the cited reference. Reconsideration and allowance is respectfully requested.

§103 Rejection of the Claims

Claims 5 and 8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) as applied to claim 1 above, and further in view of Vachon et al. (U.S. Patent No. 5,324,324).

Applicant traverses the obviousness rejection since there is no suggestion to combine the references and, even if combined, the cited combination does not include each limitation recited in the claim. For instance, Applicant cannot find in the asserted combination: “wherein the electrode includes a coating on at least a portion of a surface of the electrode, the coating including two or more layers, with a first layer adjacent the surface of the electrode including an insulative material and a second layer adjacent the first layer including at least one pharmacological agent,” as recited in parent claim 1. Neither reference includes such subject matter. Again, Stokes discusses a sintered metal porous coating 34 and a plug 38 that includes drugs that can elute through coating 34. However, sintered metal porous coating 34 is not insulative, as claimed. Likewise, as discussed above, nowhere in Vachon is the sheath 24 at least partially covered with a second layer comprising a polymer and at least one pharmacological agent.

Regarding claim 8, the Office Action asserts “it would have been obvious ... to modify the polymeric base coat as taught by Stokes, to be ethylene vinyl alcohol, since it is well known in the art that hydrophilic polymers are easily absorbed by the body with no adverse effects and, advantageously, can deliver therapeutic agents effectively.” (Page 6 of Office Action). Applicant traverses this taking of Official Notice and, pursuant to M.P.E.P. § 2144.03, Applicant

respectfully requests that the Examiner cite references in support of this position.

Reconsideration and allowance is respectfully requested.

Claims 9-10, 15 and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) as applied to claims 1 and 30 above, and further in view of MacGregor (U.S. Patent No. 4,281,669).

Claims 9-10 and 15

Applicant traverses the obviousness rejection since there is no suggestion to combine the references and, even if combined, the cited combination does not include each limitation recited in the claim. For instance, Applicant cannot find in the asserted combination: “wherein the electrode includes a coating on at least a portion of a surface of the electrode, the coating including two or more layers, with a first layer adjacent the surface of the electrode including an insulative material and a second layer adjacent the first layer including at least one pharmacological agent,” as recited in parent claim 1. Neither reference includes such subject matter. Again, Stokes discusses a sintered metal porous coating 34 and a plug 38 that includes drugs that can elute through coating 34. Likewise, the MacGregor reference does not discuss a first layer adjacent to the electrode surface including an insulative material. Reconsideration and allowance is respectfully requested.

Claim 32

Applicant traverses the obviousness rejection since there is no suggestion to combine the references and, even if combined, the cited combination does not include each limitation recited in the claim. For instance, Applicant cannot find in the asserted combination “an inner layer including a pharmacological agent in a polymer matrix for regulated, chronic release of the pharmacological agent and an outer layer including only a pharmaceutical agent such that the pharmaceutical agent of the outer layer is exposed to tissue upon implant of the electrode, and a middle layer between the inner layer and the outer layer, the middle layer including a porous polymer barrier,” as recited in parent claim 30. Reconsideration and allowance is respectfully requested.

Claim 11 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) and MacGregor (U.S. Patent No. 4,281,669) as applied to claim 9 above, and further in view of Vachon et al. (U.S. Patent No. 5,324,324).

Applicant traverses the obviousness rejection since even if combined, the cited combination does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited combination “wherein the electrode includes a coating on at least a portion of a surface of the electrode, the coating including two or more layers, with a first layer adjacent the surface of the electrode including an insulative material and a second layer adjacent the first layer including at least one pharmacological agent,” as recited in parent claim 1. Reconsideration and allowance is respectfully requested.

Claims 38-40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon et al. (U.S. Patent No. 5,324,324) as applied to claim 35 above, and in view of MacGregor (U.S. Patent No. 4,281,669).

Applicant traverses the obviousness rejection since even if combined, the cited combination does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited combination: coating an electrode with a first layer, wherein the first layer comprises a polymeric base coat; and coating the electrode with a second layer, wherein the second layer comprises a polymer and at least one pharmacological agent, and at least partially coats the first layer, as recited in parent claim 35. Reconsideration and allowance is respectfully requested.

Claims 37 and 43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon et al. (U.S. Patent No. 5,324,324) as applied to claims 36 and 42 above, and in view of Stokes (U.S. Patent No. 4,506,680).

Applicant traverses the obviousness rejection since even if combined, the cited combination does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited combination: coating an electrode with a first layer, wherein the first layer

comprises a polymeric base coat; and coating the electrode with a second layer, wherein the second layer comprises a polymer and at least one pharmacological agent, and at least partially coats the first layer, as recited in parent claim 35. Reconsideration and allowance is respectfully requested.

Claims 21-24 and 28-29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680).

Claims 21-25 and 28-29 include each limitation of parent claim 16 and are not obvious in view of the cited reference for the reasons given above. Moreover, Applicant respectfully traverses the single reference rejection under 35 U.S.C. § 103 since not all of the recited elements of the claims are found in the Stokes reference. Since all the elements of the claim are not found in the reference, Applicant assumes that the Examiner is taking Official Notice of the missing elements. Applicant respectfully objects to the taking of Official Notice with a single reference obviousness rejection and, pursuant to M.P.E.P. § 2144.03, Applicant respectfully traverses the assertion of Official Notice and requests that the Examiner cite references in support of this position.

Claims 25 and 27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) as applied to claim 21 above, and further in view of MacGregor (U.S. Patent No. 4,281,669).

Applicant traverses the obviousness rejection since even if combined, the cited combination does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited combination: “wherein an outer surface of the electrode is coated with two or more layers comprising a first layer including an insulative material and a second layer over the first layer, the second layer including at least one pharmacological agent,” as recited in parent claim 16. Reconsideration and allowance is respectfully requested.

Claim 26 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) and MacGregor (U.S. Patent No. 4,281,669) as applied to claim 25 above, and further in view of Vachon et al. (U.S. Patent No. 5,324,324).

Claim 26 includes each limitation of parent claim 16 and is not obvious in view of the cited reference for the reasons given above. Reconsideration and allowance is respectfully requested.

Claims 2, 17 and 31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) as applied to claims 1, 16 and 30 above, and in view of Berthelsen (U.S. Patent No. 4,953,564).

Applicant traverses the obviousness rejection since even if combined, the cited combination does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited combination “wherein the electrode includes a coating on at least a portion of a surface of the electrode, the coating including two or more layers, with a first layer adjacent the surface of the electrode including an insulative material and a second layer adjacent the first layer including at least one pharmacological agent,” as recited in parent claim 1; or “wherein an outer surface of the electrode is coated with two or more layers comprising a first layer including an insulative material and a second layer over the first layer, the second layer including at least one pharmacological agent,” as recited in parent claim 16; or “an inner layer including a pharmacological agent in a polymer matrix for regulated, chronic release of the pharmacological agent and an outer layer including only a pharmaceutical agent such that the pharmaceutical agent of the outer layer is exposed to tissue upon implant of the electrode, and a middle layer between the inner layer and the outer layer, the middle layer including a porous polymer barrier,” as recited in parent claim 30. Reconsideration and allowance is respectfully requested.

Claims 44-45 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon et al. (U.S. Patent No. 5,324,324) as applied to claim 35 above, and in view of Berthelsen (U.S. Patent No. 4,953,564).

Applicant traverses the obviousness rejection since even if combined, the cited combination does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited combination: coating an electrode with a first layer, wherein the first layer comprises a polymeric base coat; and coating the electrode with a second layer, wherein the second layer comprises a polymer and at least one pharmacological agent, and at least partially

coats the first layer, as recited in parent claim 35. Reconsideration and allowance is respectfully requested.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney at (612) 359-3267 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.


Respectfully submitted,

CHRISTOPHER P. KNAPP ET AL.

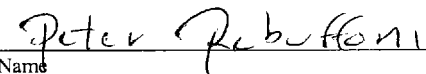
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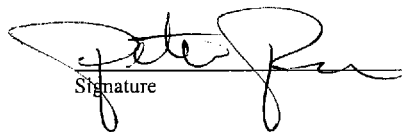
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 27 day of April, 2006.


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